

Claims allowed in 09/713,512

TECH CENTER 1600/2900

EXHIBIT 1

Clean copy of pending claims pursuant to 37 CFR 1.121(c)(3)

36. (Amended) A polyamine derivative, or salt thereof, wherein said derivative has the formula R_1 -X- R_2 .

wherein R₁-X- is of the formula R-NH-CR'R"-CO-,

wherein -NH-CR'R"-CO- is a D- or L- form of valine, asparagine, or glutamine, or the

D- form of lysine or arginine;

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wherein R" is H, CH₃, CH₂CH₃, or CHF₂;

wherein R is H or a head group selected from the group consisting of a straight or branched C_{1-10} aliphatic, alicyclic, single or multiring aromatic, single or multiring aryl substituted aliphatic, aliphatic-substituted single or multiring aromatic, a single or multiring heterocyclic, a single or multiring heterocyclic-substituted aliphatic and an aliphatic-substituted aromatic; and

wherein R₂ is a polyamine.

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 37. The derivative of claim 36 wherein R is H.
- The derivative of claim 37 wherein -NH-CR'R"-CO- is the D- form of lysine.
- 4 $\frac{7}{39}$. The derivative of claim 38 wherein R_2 is spermine.
- The derivative of claim 39 wherein R_1 -X- is attached to spermine at the N_1 position of spermine.
- AT. A composition comprising a polyamine derivative or salt according to any one of claims 36-39 and one or more pharmaceutically acceptable excipients.
 - 42. The composition of claim of further comprising a polyamine synthesis inhibitor.
- The composition of claim 42 wherein said inhibitor is difluoromethylornithine (DFMO).

- The composition of claim At wherein said one or more pharmaceutical excipients are suitable for treating a disease or condition in which the inhibition of polyamine transport is desirable.
- The composition of claim 41 further comprising one or more auxiliary agents or one or more liquid carriers.
- A6. The composition of claim 45 comprising a preservative or a stabilizer or both as said auxiliary agent.
 - The composition of claim 46° comprising a stabilizer as an auxiliary agent.
- 48. The composition of claim 45 comprising peanut oil or olive oil as said liquid carrier.
 - 49. The composition of claim 45 further comprising water.
 - The composition of claim 41 formulated as a solid.
- The composition of claim 50 formulated as a capsule, impregnated wafer, tablet or powder.
- 52. A method comprising contacting a cell with a polyamine derivative or salt according to any one of claims 36-39.
 - The method of claim 52° wherein polyamine transport in said cell is inhibited.
- 54. The method of claim 52 wherein said cell is in a subject with a disease or condition associated with undesired cell proliferation.

- 55. The method of claim 54 wherein said undesired cell proliferation is associated with proliferation of cells of the immune system, cells of the vascular neontima, tumor cells, or with undesired angiogenesis.
- The method of claim 55 wherein said disease or condition is cancer or post-angioplasty injury.
- The method of claim 54 wherein said contacting is administration of said polyamine derivative or salt to said subject systemically or topically.
- 58. The method of claim 54 wherein said contacting is administration of said polyamine derivative or salt to said subject orally, parenterally, transdermally, intravaginally, intransally, intrabronchially, intracranially, intraocularly, intraaurally, rectally, by infusion, or by injection.
- 59. The method of claim 58 wherein said administration by injection is intravenous, subcutaneous, intramuscular, intracranial, or intraperitoneal.
- 60. (Amended) A method comprising contacting a cell with a polyamine derivative or salt thereof, wherein said derivative has the formula R₁-X-R₂.

wherein R₁-X- is of the formula R-NH-CR'R"-CO-, wherein -NH-CR'R"-CO- is the L- form of lysine or arginine; wherein R" is H, CH₃, CH₂CH₃, or CHF₂;

wherein R is H or a head group selected from the group consisting of a straight or branched C₁₋₁₀ aliphatic, alicyclic, single or multiring aromatic, single or multiring aryl substituted aliphatic, aliphatic-substituted single or multiring aromatic, a single or multiring heterocyclic, a single or multiring heterocyclic-substituted aliphatic and an aliphatic-substituted aromatic; and R₂ is a polyamine

under conditions such that polyamine transport in said cell is inhibited.

- 57. The method of claim 60 wherein R" and R are H; R₂ is spermine; and R₁-X- is attached to R₂ at the N₁ position of spermine.
- 62. The method of claim 60 or 61 wherein polyamine transport in said cell is inhibited.
- 63. The method of claim 60 or 61 wherein said cell is in a subject with a disease or condition associated with undesired cell proliferation.
- 64. The method of claim 63 wherein said undesired cell proliferation is associated with proliferation of cells of the immune system, cells of the vascular neontima, tumor cells, or with undesired angiogenesis.
- The method of claim 64 wherein said disease or condition is cancer or post-angioplasty injury.
- 66. The method of claim 63 wherein said contacting is administration of said polyamine derivative or salt to said subject systemically or topically.
- 67. The method of claim 63 wherein said contacting is administration of said polyamine derivative or salt to said subject orally, parenterally, transdermally, intravaginally, intranasally, intrabronchially, intracranially, intraocularly, intraaurally, rectally, by infusion, or by injection.
- 68. The method of claim 67 wherein said administration by injection is intravenous, subcutaneous, intramuscular, intracranial, or intraperitoneal.
- 69. A method comprising contacting a cell with a polyamine derivative or salt according to any one of claims 36-39 and a polyamine synthesis inhibitor.
 - 70. The method of claim 69 wherein said inhibitor is DFMO.

- 7. The method of claim wherein polyamine transport in said cell is inhibited.
- 73
 72. The method of claim 69 wherein said cell is in a subject with a disease or condition associated with undesired cell proliferation.

23

- 77. The method of claim 32 wherein said undesired cell proliferation is associated with proliferation of cells of the immune system, cells of the vascular neontima, tumor cells, or with undesired angiogenesis.
- 74. The method of claim 73 wherein said disease or condition is cancer or post-angioplasty injury.
- 75. The method of claim 22 wherein said contacting is administration of said polyamine derivative or salt to said subject systemically or topically.
- 76. The method of claim 72 wherein said contacting is administration of said polyamine derivative or salt to said subject orally, parenterally, transdermally, intravaginally, intransally, intrabronchially, intracranially, intraocularly, intraaurally, rectally, by infusion, or by injection.
- The method of claim 76 wherein said administration by injection is intravenous, subcutaneous, intramuscular, intracranial, or intraperitoneal.
- 88. The method of claim 60 or 61, wherein said contacting further comprises contacting said cell with a polyamine synthesis inhibitor.
- 89. The method of claim 88, wherein said polyamine synthes is inhibitor is α -difluoromethylornithine.

90. The method of claim, 88 wherein said cell is in a subject with a disease or condition associated with undesired cell proliferation.

The method of claim 89 wherein said cell is in a subject with a disease or condition associated with undesired cell proliferation.

92. The method of claim 90 wherein said undesired cell proliferation is associated with cancer.

32. The method of claim of wherein said undesired cell proliferation is associated with cancer.

94. The method of claim 54-wherein said undesired cell proliferation is associated with cancer.

95. The method of claim 63 wherein said undesired cell proliferation is associated with cancer.